Effects of structured testing versus routine testing of blood glucose in diabetes self-management: A randomized controlled trial

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Effects of structured testing versus routine testing of blood glucose in diabetes self-management: A randomized controlled trial

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Short running title:

Structured vs. routine SMBG self-management

Abstract

Aims:

To compare the effects of structured and routine testing regimens used in self-monitoring of blood glucose (SMBG) on glycemic control and diabetes self-management in insulin-naïve type 2 diabetes patients.

Methods:

Sixty-two outpatients with insulin-naïve type 2 diabetes were randomly allocated into two less-frequent SMBG usage groups: a structured testing group (STG) and a routine testing group (RTG). Subjects in STG measured 7-points on SMBG for 3 consecutive days once every two months without daily testing; subjects in RTG measured SMBG 3 times each week before breakfast on Monday and Friday and before dinner on Wednesday. The primary endpoint was HbA1c reduction. The secondary endpoints were change in body weight, blood pressure, treatment change, and self-management performance change.

Results:

HbA1c levels were significantly decreased by 0.32% (3.50 mmol/mol) in STG, partly because physicians changed medications more actively. In contrast, body weight and systolic/diastolic blood pressure were significantly reduced by 0.94 kg and 6.8/4.7 mmHg, respectively, in RTG, possibly related to the increased diet and exercise score in RTG.

Conclusions:

Structured testing without daily testing is beneficial for glycemic control; routine testing 3 times a week is more helpful for daily self-management. In low SMBG frequency usage, these two regimens can be utilized according to individual diabetic conditions.

Keywords:

Glycemic control
Non-insulin treated type 2 diabetes
Self-management
Self-monitoring of blood glucose
SMBG

1. Introduction

Self-monitoring of blood glucose (SMBG) is a useful tool for patients to prevent hypoglycemia and to adjust diet and physical activity (AADE, 2008; International Diabetes Federation, 2009). SMBG is also important for physicians to adjust medication (International Diabetes Federation, 2012). These benefits of SMBG for insulin-treated type 2 diabetes patients are well established (American Diabetes Association, 2016). On the other hand, no consensus on improvement of glycemic control by SMBG has been obtained in insulin-naïve patients, even though evidence of the general benefits of SMBG has been increasing in the last decade. Previous studies show that the effects of simply measuring blood glucose in insulin-naïve patients are minimal (St John et al., 2010; Farmer et al., 2012; Malanda et al., 2012). However, when individuals with insulin-naïve type 2 diabetes perform SMBG frequently, glycemic control has been shown to be improved (Harashima et al., 2013; Elgart et al., 2016) as also in type 1 (Miller et al., 2013) and insulin-treated type 2 diabetes (Elgart et al., 2016).

However, frequent and/or regular SMBG can lead to economic barriers and have a negative impact on health care budget (Klonoff et al., 2011). The subtle relationship between cost and effects of SMBG on diabetes management has been a concern around the world. In the United States, Medicare contractors paid more than $1.2 billion for test strips and/or lancets in 2007 (Department of Health & Human Services, Office of the Inspector General, 2011). On the other hand, SMBG might facilitate the achievement of treatment goals and so decrease the cost of care (Tunis et al., 2010a). The American Diabetes Association recommends that the ongoing need and frequency of SMBG should be reevaluated at each routine visit to avoid excessive use. (American Diabetes Association, 2016). In Canada, $247 million were spent on blood glucose test strips by publicly funded drug programs in 8 Canadian provinces (Cameron et al., 2010a). An incremental cost of $113,643 per quality-adjusted life-year gained was identified for insulin-naïve type 2 diabetes patients using 7 strips per week compared with no testing (Cameron et al., 2010b). The Canadian Diabetes Association clinical guidelines recommend that the frequency of SMBG should be based on the risk of hypoglycemia, the type of medication used, and the state of glycemic control in insulin-naïve patients; infrequent SMBG being appropriate for patients with good glycemic control. On the other hand, in Italy, greater utilization of test strips was reported to be associated with a significantly reduced number and reduced duration of hospitalizations for diabetes patients, which results in saving of overall health care costs despite the increase in the direct costs of test strips (Giaccari et al., 2012). An international study also found that SMBG is cost-effective with regard to diabetes complications in the long term (Tunis et al., 2010b). This evidence suggests that lower-frequency SMBG might be effective for insulin-naïve patients in daily self-management and improvement of glycemic control.

A key to improving glycemic control with less frequent SMBG is responsive action by the patients themselves. Recently, we reported that color record in SMBG has a favorable effect on self-management performance without any influence on psychological stress and that it results in improved glycemic control in less frequently insulin-treated type 2 diabetes patients (Nishimura et al., 2014). Maintenance of SMBG once a day in insulin-naïve patients has been shown to keep better glycemic control compared with cessation of SMBG due to improved motivation to diet therapy (Harashima et al., 2016). Recently, Polonsky reported that structured testing has a beneficial effect on glycemic control. Self-monitoring of seven-points on an SMBG device for 3 consecutive days once every three months in addition to daily tests resulted in better glycemic control compared to the active control group (Polonsky et al., 2011). Structured testing is a new method of less-frequent SMBG that guides glycemic management strategies and has the potential to improve problem-solving and decision-making skills for both patients and clinicians (Fisher et al., 2012; Scavini et al., 2013). Evidence suggests that less frequent SMBG can have favorable effects on glycemic control when both healthcare providers and patients appreciate the purpose of their SMBG measurements.

In consideration of SMBG cost and patient well-being, a simpler and more economical SMBG method is an unmet need in diabetes management. We conduct here a clinical research study comparing two SMBG methods involving less frequent usage, i.e., structured testing without daily testing and routine testing three times a week, to ascertain the effects of lower frequency SMBG on glycemic control and diabetes self-management in insulin-naïve type 2 diabetes patients. The total number of SMBG tests was less than 25 times bimonthly in both of these testing regimens.

2. Subjects, Materials and Methods

2.1. Study design

The study is a prospective, randomized, controlled, single center, open trial to evaluate the effect of two SMBG regimens for use in insulin-naïve type 2 diabetes patients, i.e., structured testing (ST) and routine testing (RT), on glycemic control. The study protocol was approved by the Institutional Review Board of Kyoto University (C671) in compliance with the Helsinki Declaration and prospectively registered on University hospital Medical Information Network (UMIN8965). Written informed consent was obtained from all subjects.

2.2. Participants

Inclusion criteria were: insulin-naïve type 2 diabetes; no experience of SMBG; age 20 years or older; HbA1c level between 6.0 and 10.5% (between 42.1 and 91.3 mmol/mol); and ability for diet and/or exercise therapy. Exclusion criteria were: diabetes duration < 1 year; treatment with insulin or GLP-1 receptor agonists; severe comorbidities (e.g., severe cardiovascular disease, liver and renal disorders, malignancy); depression or psychiatric problems; impaired vision or synesthesia; abnormal hemoglobinemia; pregnancy; inability to follow trial procedures; and those patients judged unsuitable for this study by physicians.

Study subjects were recruited between 13 May and 25 September 2014 from the outpatient department of a university hospital in Kyoto, Japan. Subjects were screened for eligibility by a trained group of assessors (two certified diabetes educators and a diabetologist). Subjects were assigned to one of the two groups, the structured testing group (STG) or the routine testing group (RTG) (1:1 ratio), with an allocation code using balanced design (age, gender, HbA1c, diabetes duration) in consecutively numbered sealed envelopes. The allocation code was randomly generated using number generator software. The generation of the allocation code and the assignment of the participants were carried out by independent persons.

Sixty-two subjects without any experience in SMBG were recruited for the study: 30 in STG and 32 in RTG. No subjects dropped out during the study (Figure 1). Average age of STG and RTG was 66.7 ± 12.5 years and 65.8 ± 8.5 years, respectively; the ratio of females was 36.7% and 40.6%; duration of diabetes was 13.3 ± 8.4 years and 14.1 ± 8.7 years; body weight was 65.3 ± 10.4 kg and 65.8 ± 14.0 kg; and HbA1c levels were 7.21 ± 0.75% (55.3 ± 8.2 mmol/mol) and 7.21 ± 0.51% (55.3 ± 5.6 mmol/mol) (Table 1). There was no significant difference in subject background including blood pressure and lipid profiles.

2.3. Intervention

All subjects were provided with a blood glucose meter (Accu Check Aviva Nano™; Roche Diagnostics K.K., Japan). They used the meter to record blood glucose levels during the study on a 360° view sheet in STG and in self-monitoring notes in RTG. Self-monitoring notes are provided by the Japan Association for Diabetes Education and Care (JADEC), and are commonly used by patients to record blood glucose levels in Japan. Subjects in STG measured 7-points on SMBG for 3 consecutive days once every two months without daily testing; subjects in RTG measured SMBG 3 times each week before breakfast on Monday and Friday and before dinner on Wednesday. The total number of SMBG sessions was less than 25 times bimonthly in both regimens.

The study duration was 24 weeks and all subjects visited the hospital every 8 weeks. All subjects watched a 15-minute video instructing use of the meter, recording method and interpretation of blood glucose levels at enrollment and were provided with the instruction DVD. They also were provided usual lifestyle intervention by independent healthcare staff at every visit.

2.4. Outcome measures

The primary endpoint was the difference in change in HbA1c at 24 weeks between STG and RTG. The secondary endpoints were differences in body weight, blood pressure, and self-management performance change between STG and RTG. Self-management performance was evaluated by The Summary of Diabetes Self-Care Activities Measure (SDSCA) (Toobert et al., 2000; Daitoku et al., 2006). All subjects completed a questionnaire, a blood test and blood pressure measurement at each visit with their primary physicians. A trained nurse collected all questionnaires, measurements and data blindly.

2.5. Sample size

The optimal sample size calculation was based on results of previous research, using JMP Pro 12.2.1. (SAS Institute Japan Inc., Tokyo, Japan). The study was designed to have 80% power to detect difference of 0.4% in change in HbA1c levels at a two-sided significance level of $p < 0.05$. We estimated the standard deviation of change in HbA1c levels to be 0.5%. The required sample size was 26 participants for each group to achieve the specified statistical power. Another 10% was added to the calculation to allow for withdrawals from the study. A total of 60 patients were required.

2.6. Statistical analysis

Data were expressed as means and standard deviations, and categorical data as frequency and percentage. Independent sample Student's t-test was used to compare the mean of HbA1c levels between STG and RTG. HbA1c outcomes were assessed for statistical analysis blindly. Independent sample Student's t-test was also used to compare the baseline differences and the change differences in all continuous variables between STG and RTG. Baseline group differences in the proportion of gender were analyzed by chi-square tests. Paired t-tests were used to compare the means of HbA1c levels, body weight, blood pressure, lipids profiles and the score of questionnaires between baseline and 24 weeks in STG and RTG. The intention-to-treat analysis was conducted. The statistical analyses were performed using SPSS 20.0 (IBM Japan Inc., Tokyo, Japan). P values < 0.05 were considered as statistically significant.

3. Results

3.1. *HbA1c findings*

HbA1c levels were significantly decreased from 7.21 ± 0.75% (55.3 ± 8.2 mmol/mol) to 6.93 ± 0.78% (52.2 ± 8.5 mmol/mol) in STG, but were not significantly decreased from 7.21 ± 0.51% (55.3 ± 5.6 mmol/mol) to 7.10 ± 0.64% (54.1 ± 7.0 mmol/mol) in RTG (Figure 2A). The change in HbA1c levels at 24 weeks was -0.28% (-3.1 mmol/mol) (95% CI: -0.51 to -0.05% [-5.8 to -0.5 mmol/mol], $p < 0.05$) in STG and -0.11% (-1.2 mmol/mol) (95%CI: -0.30 to 0.08 [-3.3 to 0.9 mmol/mol]) in RTG (Figure 2B). There was no significant difference in change in HbA1c between STG and RTG.

3.2. *Body weight, blood pressure, and lipid profiles*

Body weight was significantly decreased from 65.8 ± 14.0 kg to 64.9 ± 14.0 kg in RTG, but was not significantly decreased in STG (from 64.6 ± 9.9 kg to 64.1 ± 9.6 kg) (Figure 3A). The change in body weight at 24 weeks was -0.48 kg (95% CI: -1.01 to 0.06) in STG and -0.84 kg (95%CI: -1.37 to -0.30, $p < 0.01$) in RTG.

Systemic and diastolic blood pressures were significantly decreased from 138.6 ± 19.4 mmHg to 130.8 ± 18.0 mmHg, and 79.5 ± 12.2 mmHg to 75.5 ± 9.5 mmHg, respectively, in RTG, but were not significantly decreased in STG (from 136.8 ± 18.1 mmHg to 135.3 ± 17.9 mmHg and from 79.1 ± 11.0 mmHg to 77.6 ± 12.9 mmHg). The change in systemic and diastolic pressures at 24 weeks were -1.52 mmHg (95% CI: -6.0 to 2.9) and -1.4 mmHg (95%CI: -4.5 to 1.6), respectively, in STG, and -7.8 mmHg (95%CI: -12.9 to -2.8, $p < 0.01$) and -3.9 mmHg (95%CI: -7.2 to -0.7, $p < 0.05$) in RTG (Figure3B).

Lipid profiles were not changed in STG and RTG during the study (data not shown).

3.3. *Treatment change*

Oral hypoglycemic agents were increased in dosage and/or more combination in STG compared to those in RTG (15 subjects (50.0%) vs. 7 subjects (21.9%), $p < 0.05$). There were no subjects whose medication was decreased in dosage or in frequency.

3.4. *Self-management performance*

The change in diet subscale score of the SDSCA at 24 weeks was 0.83 points (95%CI: 0.44 to 1.23, $p < 0.001$) in RTG, and -0.03 points (95%CI: -0.44 to 0.39) in RTG (Figure 3C). The change in diet subscale of the SDSCA at 24 weeks was significantly increased in RTG compared to that in STG (0.86, 95%CI: 0.30 to 1.42, $p < 0.01$). The change in exercise subscale score of the SDSCA at 24 weeks was 0.72 points (95%CI: 0.11 to 1.33, $p < 0.05$) in RTG, and 0.64 points (95%CI: -0.15 to 1.44) in STG (Figure 3C). The change in exercise subscale of the SDSCA at 24 weeks was not altered between STG and RTG (0.08, 95%CI: 0.30 to 1.42, $p < 0.01$). Medication subscale of the SDSCA was not changed during the study in either group.

4. Discussion

Higher frequency of SMBG is useful for glycemic control in both type 1 and type 2 diabetes (Elgart et al., 2016; Miller et al., 2014; Harashima et al., 2013). However, partly due to the increase in medical cost, higher frequency SMBG often is not recommended, especially for insulin-naïve diabetes patients (Tunis et al., 2010b; Cameron et al., 2010a). In addition, lower frequency SMBG, for example once daily, may not be useful for glycemic control (Malanda et al., 2012; Farmer ete al., 2012; Clar et al., 2010). Recently it was reported that structured testing can have a beneficial effect on glycemic control (Polonsky et al., 2011). Patient monitoring of seven-points on an SMBG device for 3 consecutive days once every three months in addition to daily tests resulted in better glycemic control compared to the active control group. More structured testing patients received a treatment change recommendation at the month 1 visit compared with active control patients. The number of daily SMBG tests in month 12 was 0.69 times that in structured testing patients, while it was 1.05 times that in active control patients. A SMBG-OHA follow-up study showed that at least once daily SMBG is helpful to maintain glycemic control in insulin-naïve type 2 diabetes (Harashima et al., 2016). This evidence indicates that less frequent SMBG may have a good effect on glycemic control.

However, the previous study also shows that financial barriers reduce use of SMBG by patients (Karter et al., 2003; Karter et al., 2007). The cost of SMBG is an important issue in Japan, especially for insulin-naïve diabetes patients, as health insurance does not cover such SMBG cost. If patients do SMBG tests once daily, the cost to them is about 35 dollars a month for strips. They often do not perform SMBG routinely, therefore. Many patients wish for a more liberal SMBG policy for their self-management with oral hypoglycemic agents alone. A simpler, more efficient, and decidedly more economical SMBG method is an unmet need of clinical type 2 diabetes control.

Structured testing represents a beneficial way to monitor blood glucose levels with less frequent SMBG tests, but it is not clear whether routine testing is beneficial for glycemic control when the total number of monthly SMBG tests is almost the same as that in structured testing. In the present study, we found that structured testing once bimonthly without daily testing is useful for glycemic control compared to routine testing three times each week, while routine testing is more helpful for daily self-management than structured testing. Diabetes medications were changed more often in structured testing. This was one of major factors in the improvement of glycemic control, in accord with the previous study (Bosi et al., 2013; Polonsky et al., 2011). On the other hand, less frequent routine testing showed improved self-management performance, blood pressure and body weight, although glycemic control was not improved. The majority of patients rely on SMBG to evaluate their self-management efforts (Tanenbaum et al., 2015). In our study, participants in routine testing three times a week were able to review their diabetes-specific behavior changes and their efforts through blood glucose levels. In addition to glycemic control, control of blood pressure and body weight are very important in diabetes management. These factors all contribute to reduce the risk of diabetes complications in the long term (Gaede et al., 2008). Thus, these two SMBG regimens might be adapted on a case-by-case basis to obtain optimum beneficial effects of SMBG with less frequent testing.

In fact, SMBG may have a negative impact on well-being (Simon et al., 2008). It is reported that an SMBG frequency of ≥1 per day is related to higher levels of distress, worry, and depressive symptoms in insulin-naïve patients (Franciosi et al., 2001). Inexplicable readings can be distressing, resulting in a sense of personal “failure” with unexpected values of glucose levels (Peel et al., 2004). However, structured SMBG was not associated with deterioration of quality of life and locus of control (Russo et al., 2016). Our study also showed that mood status was not affected by lower frequency SMBG tests, in that no participants dropped out of the study and they all followed the study protocol nearly perfectly. Thus, an SMBG frequency of < 1 per day may be not related to psychological burden.

There are limitations to our study. First, subjects were recruited in a single hospital, so that the characteristics of participants were biased. Second, although blood pressure, body weight, and lipid profiles were evaluated in our study, other self-management-related factors such as exercise amount, salt intake and sleep were not investigated. Further studies involving a larger number of patients are needed.

In conclusion, structured testing is beneficial for glycemic control, while routine testing is helpful for daily self-management. Utilizing lower SMBG frequency, these two regimens can be employed according to individual diabetic conditions.

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Table 1

Demographic profiles and baseline data of study subjects.

Variables	STG n = 30	RTG n = 32	*p value*
Age (years)	66.7 ± 12.5	65.8 ± 8.5	0.744
Female (%)	36.7	40.6	0.799
Diabetes duration (years)	13.3 ± 8.4	14.1 ± 8.7	0.705
HbA1c (%)	7.21 ± 0.75	7.21 ± 0.51	0.988
(mmol/mol)	(55.3 ± 8.2)	(55.3 ± 5.6)	
Body weight (kg)	65.3 ± 10.4	65.8 ± 14.0	0.884
Systemic blood pressure (mmHg)	136.8 ± 18.1	138.6 ± 19.4	0.727
Diastolic blood pressure (mmHg)	79.1 ± 11.0	79.5 ± 12.2	0.904
Total cholesterol (mg/dl)	178.1 ± 37.4	175.0 ± 30.6	0.740
High-density lipoprotein cholesterol (mg/dl)	53.5 ± 16.1	54.7 ± 13.4	0.777
Low-density lipoprotein cholesterol (mg/dl)	99.7 ± 30.9	101.7 ± 28.6	0.817

Data are means ± SD. STG, structured testing group; RTG, routine testing group

Figure 1

Flow chart of the participants

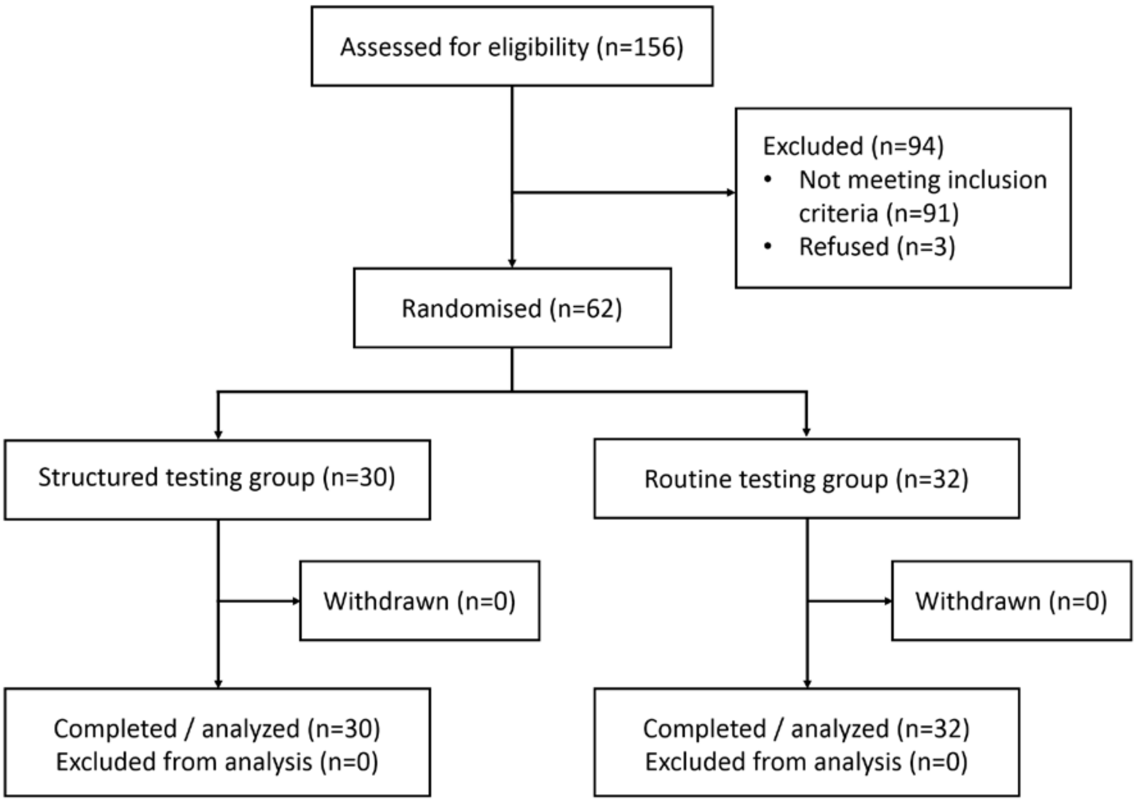

Figure 2

Time course (A) and change (B) in HbA1c levels during the study. STG, structured testing group; RTG, routine testing group

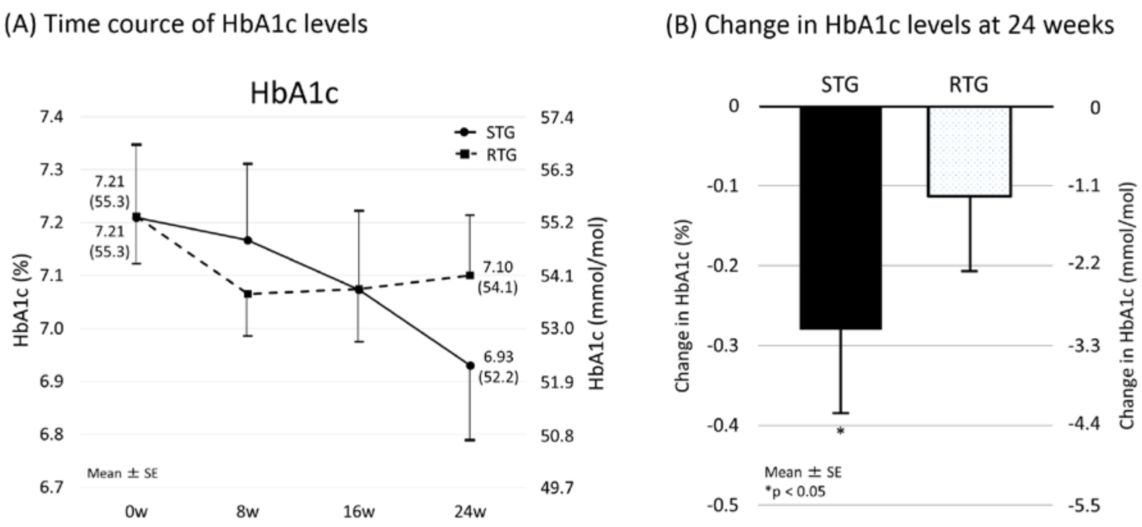

Figure 3

Change in body weight (A), blood pressure (B) and self-management performance (C) during the study. STG, structured testing group; RTG, routine testing group